UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,205	01/12/2001	Ralf Zielenski	RDID0013US	2666

23690 7590 09/22/2003

Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457

EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	18

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,205	ZIELENSKI, RALF	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-45* is/are pending in the application.

4a) Of the above claim(s) *26-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 18 – 25 in Paper No. 15 is acknowledged. The traversal is on the grounds that examiner has not set forth convincing reasons for the distinctness of the groups and that the groups were previously kept together and can therefore not be separated. This is not found persuasive because as evidenced by US 6,162,615 (applicant's own work), other materially different products are known to determine concentration of substrates. In addition, applicant is directed to US 5188941, US 5061619 and US 4753875 for methods using antibody-antigen binding to determine substrate concentrations in samples. It is reiterated that the several inventions are distinct as indicated by the separate classification. Regarding the inventions that were previously examined together, Applicant is directed to MPEP 811, and 37 CFR 1.142(a), second sentence which states: "[i]f the distinctness and independence of the invention be clear, such requirement will be made before any action upon the merits; however, it may be made at any time before final action in the case at the discretion of the examiner."

The requirement is still deemed proper and is therefore made FINAL.

Claims 26 – 45 are withdrawn from further consideration, as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 18 – 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The phrase "the solution characterized by the absence of glucose-6-phosphate dehydrogenase" recited in claim 18 is regarded new matter because neither the specification nor claims teaches or discloses a solution that specifically excludes the dehydrogenase. Moreover, the disclosure fails to describe that the absence of glucose-6-phosphate dehydrogenase is essential to the composition of the invention. As such the new limitation is new matter that was not originally described in the specification or claims, as filed.

3. Claims 18 – 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a solution comprising (a) NAD or NADP; (b) citrate/citric acid; and (c) nitrogen compounds of a specific formula, does not reasonably provide enablement for the composition comprising (b) any organic compound with a pKa value of 1.5 – 6.0. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification exemplifies a functional reagent wherein citrate is included in the composition.

However, the specification fails to set forth a representative number of other organic compounds with a pKa of 1.5 – 6.0, that would enable one in the art to make or use the composition of the invention. Since a wide array of organic compounds with a variety of function and structure have a pKa of 1.5 – 6.0, it would be nearly impossible for one in the art to know which organic compound would be appropriate to the invention. Moreover, the specification fails to enable one in the art how to make and use the composition of the invention with any organic compound with a pKa of 1.5 – 6.0.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 18 – 19, 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoyama et al. (US 5783382).

Applicant claims an aqueous solution comprising a hydrogen-accepting coenzyme selected from NAD, NADP and derivatives thereof; one or more compounds selected from organic compounds or salts thereof with pKa or 1.5 – 6.0; and nitrogen compounds with a specified formula; wherein the solution does not contain glucose 6 phosphate dehydrogenase. The organic compound is citric acid or a citrate salt, the nitrogen compound is a hydroxylamine derivative or salt thereof and the solution further contains a boric acid derivative.

Aoyama teaches compositions comprising diagnostic agents and disoxidants (abstract, claims) wherein the preferred composition comprises a coenzyme, disoxidant, and buffer (col.1 line 54-57, col.2 line 61-68). Specifically, the coenzyme may be NAD or NADP (col.5 line 32-34), the disoxidant may be hydroxylamines (col.1 line 54 – col.2 line 8), and the buffer may be citrate and borate buffers (col.5 line 46-52).

Although Aoyama does not specifically disclose a composition comprising the claimed components, one in the art is able to "at once envisage" the specific combination within the generic composition. In addition, while Aoyama does not specifically exclude glucose-6-phosphate dehydrogenase, the enzyme is not essential to the reference compositions and may be excluded from the disclosed embodiments.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 18 – 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyama.

Applicant claims an aqueous solution comprising a hydrogen-accepting coenzyme selected from NAD, NADP and derivatives thereof; one or more compounds selected from organic compounds or salts thereof with pKa or 1.5 – 6.0; and nitrogen compounds with a

specified formula; wherein the solution does not contain glucose 6 phosphate dehydrogenase. The organic compound is citric acid or a citrate salt with a concentration of 5 – 200 mM; and the nitrogen compound is a hydroxylamine derivative or salt thereof with a concentration of 2 – 300 mM. The solution further contains a boric acid derivative with a concentration of 50 – 200 mM; and the pH is between 1.0 and 7.0.

Aoyama teaches stabilized compositions comprising diagnostic agents and disoxidants (abstract, claims) wherein the preferred composition comprises a coenzyme, disoxidant, and buffer (col.1 line 54-57, col.2 line 61-68). Specifically, the coenzyme may be NAD or NADP (col.5 line 32-34), the disoxidant may be hydroxylamines (col.1 line 54 – col.2 line 8), and the buffer may be citrate and borate buffers (col.5 line 46-52).

Although Aoyama does not specifically disclose a composition comprising the claimed components, one of ordinary skill in the art would have been able to "at once envisage" the specific combination within the generic composition. Moreover, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the claimed ingredients with a reasonable expectation for successfully obtaining a stabile diagnostic composition.

Although Aoyama does not specifically exclude glucose-6-phosphate dehydrogenase, the enzyme is not essential to the reference compositions and may be excluded from the disclosed embodiments.

Aoyama does not teach the specific concentrations of each component, or the pH of the compositions. However at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such variables as a matter of routine

experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts of ingredients in the compositions of Aoyama with a reasonable expectation for successfully obtaining a stabile diagnostic composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
September 11, 2003

LEON B. LANKFORD, JR.
PRIMARY EXAMINER